REMARKS

Prior to the present Office Action, claims 26, 32-36, and 39-55 were pending. Claims 26, 32-36, and 39-55 have been canceled, and claims 56-69 added. Therefore, claims 56-69 remain pending.

The claims have been amended to claim a laminated construct of a molded medical article (e.g., a molded breast implant shell) surrounded by a liner, formed within a mold of a rotational molding machine which results in a seamless product. This format is believed to be consistent with the medical article as previously claimed. Although there was a Restriction Requirement in the grandparent application, now U.S. Patent No. 6,602,452, the present claims do not claim either the system or the method for forming the medical article, instead the claims pertain to the laminated construct of the medical article and a mold liner. Such a format is disclosed in the application and thus is not new matter (e.g., see paragraph [0014] introducing the "laminated construct"). Applicants respectfully request consideration of these claims in response to the Examiner's previous rejections that disregarded process steps used to form the medical article.

Claims 32-36, 39-42, 45-49, and 51-55 stand rejected under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 4,960,425 to Yan, et al. Yan, et al. disclose a textured implant.

Between col. 3, lines 14-55, of Yan, et al. several ways to form the textured implant are described. A formed shell disposed on a disk or wrapped over a mandrel may be coated with silicone and a textured medium and then cured. A mandrel having a textured surface may be coated with silicone and then a shell, whereupon after curing the texturized shell is turned inside out. The texturing may be etched on the outer surface of a shell using various techniques such as with an ion beam. Or, a shell may be formed inside a mold having a textured surface. The latter technique is shown in Fig. 8 and described at col. 7, lines 53-63. The mold has an upper surface 54 and a lower surface 56, either of which can be texturized. The resulting molded shell will naturally exhibit a parting line, and therefore not be "seamless."

The claims are believed allowable over Yan et al. The only mention in Yan et al. of a mold having an internal mold surface within which a medical article may be formed is the above-mentioned passage at col. 7, lines 53-63 referring to Fig. 8. The mold shown is a two-part mold and the resulting molded product will naturally have a parting line where the two mold halves meet. There is no discussion of using a mold liner. Accordingly, there is no disclosure of suggestion of the laminated construct of a seamless medical article within a mold liner formed within a mold. Applicants believe that new claims 56-69 are allowable over Yan, et al.

The secondary references of Prahl (4,426,742) and Pangman (3,366,975) do not disclose much detail in the way of formation of the respective molded prosthesed, and do not mention use of a mold liner either.

Pinchuk (5,376,117) describes a rotational molding process at col. 9, lines 15-26, which utilizes a "two-piece mold cavity" and does not mention a mold liner.

The advantages of forming the medical article using the laminated construct to result in a seamless product is stated in the present application as follows:

> [0014] A second aspect of the rotational molding system and process of the present invention relates to providing a means for molding seamless articles. Most articles made by rotational molding are made using multi-part hollow molds. It is often undesirable for medical products intended for implantation to have a seam or other surface irregularities. Even with precision machining of the mold, the articles produced by conventional rotational molding processes have, at a minimum, a witness parting line in their outer surface due to the mating surfaces of the mold. These mold parting lines are eliminated in the process disclosed in the present invention by first coating the inside of the assembled, multi-part mold with a thin layer of molding material such as polyethylene, polypropylene, polyester resin or the like to create a mold liner. After the liner is cast, then the raw material, e.g. silicone, polyurethane, or other polymer, for the desired article is injected into the mold cavity and similarly rotationally cast inside the liner resulting in a laminated construct. When the mold is disassembled and the construct is removed from the mold, the liner material and the desired article are physically separated resulting in the desired article having a seamless configuration.

Based on the above amendments and remarks, Applicants believe that claims 56-69 are in condition for allowance. If there is any further hindrance to allowance, the Examiner is encouraged contact the undersigned by telephone.

Respectfully submitted,

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